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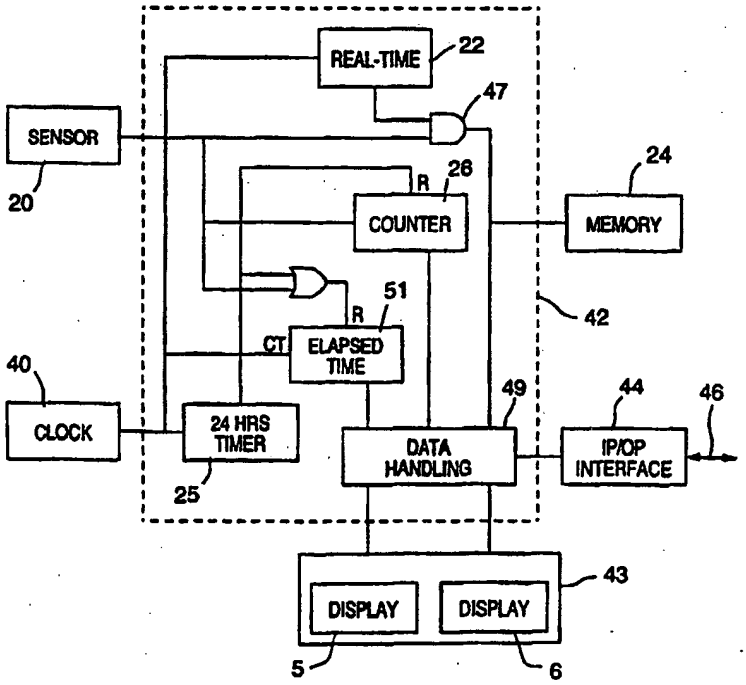
(57) Abstract

Devices and methods for providing medication dosing information to patients are disclosed. The devices note when the patient takes a dose of drug, tells the patient how many doses of drug have been taken on a daily basis, and indicates how long it has been since the last dose was taken. In one embodiment the devices include a memory (24) which can be recorded information on patient compliance for retrieval by health care professionals monitoring the patient's condition. In some embodiments the device includes a memory (24) carrying a dosing regimen which may be used to generate patient alerting signals. In some embodiments the devices include a memory (24) carrying desired dosing rate information which the device may use to gauge patient compliance. The device can inform the patient as to whether or not the determined rate matches the desired rate.



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ELECTRONIC DOSING INFORMATION DEVICE

BACKGROUND OF THE INVENTION

Field of the invention

This invention is in the field of medication monitoring. More particularly it concerns devices and methods for monitoring and assisting patients in the timely use of medication.

Description of the Prior Art

There is a growing awareness that a drug's effectiveness can be seriously compromised when the patient does not take the drug according to the prescribed schedule. It is also becoming understood that concerns about compliance with a prescribed regimen can cause worry and anxiety. This is particularly prevalent with the elderly and in situations where the condition being treated is serious and proper compliance is key to the drug's effectiveness. It is also becoming better understood that in many instances it is useful to have a record of patient self-dosing to verify medication effectiveness.

These concerns have led to the development of numerous devices and methods for facilitating and monitoring patient compliance with drug dosing regimens. These developments include simple alarms which go off when it is time to take a drug dose. (See, for example, United States Patent Number 2,853,182 of Barnett and United States Patent Number 3,369,697 of Glucksman.) They also include devices which provide additional compliance information to the patient or the patient's healthcare professional. (See, for example, United States Patent Number 3,227,127 of Gayle and United States Patent Number 4,360,125 of Martindale.) Such compliance information can range from an overview of the dosing regimen to the time of day. Other devices in the art provide signals if a dose is being requested too early or too late. Yet other devices have timer-driven lockouts which regulate patient access to the drug and thus prevent improper dosing. Another feature found in some devices of the art is memory for storing information on the patient's compliance.

(See, for example, United States Patent Number 4, 588,303 of Wirtschafter and United States Patent Number 4,970,669 of McIntosh.)

These are but a few of what has become a substantial variety of features and devices in this field. In general terms, the device developers in this field have come up with various combinations of features which, when incorporated into devices and methods, provide special advantages or serve particular needs. While one combination of features may serve the needs of a particular type of drug or a particular class of patients, in other settings it may prove seriously wanting. It is against this background that the present device and method were discovered.

STATEMENT OF THE INVENTION

The present invention provides improvements in medication dosing information devices for patient use. It also provides methods which employ these devices. The devices are simple and direct in operation and provide patients with combinations of information which can be most effective in promoting compliance with the medication regimen. This effectiveness is a result of the device providing patients those pieces of compliance information which they most keenly want to know. This compliance information can improve compliance with a regimen and can lower patient anxiety.

The devices of the present invention, in their most fundamental form, note when the patient takes a dose of drug, tell the patient how many doses of drug have been taken on a daily basis and indicates how long it has been since the last dose was taken.

In one embodiment the devices include a memory which can record information on patient compliance. This information can be retrieved and used by the health care professionals monitoring the patient's condition.

In some embodiments the devices include a memory into which a regimen of desired drug dosing times is loaded. These times are retrieved out of memory and used to generate alerting signals to aid the patient's timely adherence to the dosing regimen.

In yet other embodiments the devices are equipped to determine the rate at which medication events are being detected and to compare this determined rate with previously provided acceptable or preferred medication event rate values. The patient can then be informed as to whether or not the determined rate fits within the acceptable/preferred rates. This information can help the patient adhere to the prescribed regimen. In a preferred embodiment of this type of device, the device focuses on patient overdosing and informs the patient if the determined medication event rate exceeds the acceptable/preferred rate.

In another aspect, this invention provides methods for monitoring and enhancing a patient's compliance with drug dosing regimens. In one general sense, these methods involve administering a drug dosing regimen with the assistance of one of the devices of the invention.

In one such method a patient's compliance with a drug dosing regimen is monitored and enhanced by providing the patient two pieces of information throughout the dosing period - the number of doses taken on a current daily basis and the length of time since the patient's last dose - and additionally compiling and storing a record of the patient's dosing events which can later be accessed by the patient's health care professionals. This method can also provide alerts to the patient consistent with the desired drug dosing regimen.

In another such method a patient's compliance with a drug dosing regimen is monitored and enhanced by providing the patient the same two pieces of information throughout the dosing period - the number of doses taken on a current daily basis and the length of time since the patient's last dose - and additionally determining the rate at which the patient is taking doses, comparing this determined rate with a previously supplied acceptable or preferred rates of dosing and then indicating to the patient whether or not the determined rate falls within the acceptable/preferred rates.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective illustration of an electronic dosing information device implemented in a medication bottle cap.

FIG. 2 is a top view of the electronic dosing information device of FIG. 1.

FIG. 3 is a schematic illustration of a generalized electronic section of an electronic dosing information device.

FIG. 4 is a more detailed schematic illustration of a generalized electronic section of an electronic dosing information device.

DETAILED DESCRIPTION OF THE INVENTION

The devices of this invention detect when "medication events" occur. These medication events are the taking or accessing by the patient or dispensing to the patient of medication. This medication is usually provided in a discrete unit dosage form such as a pill, tablet, metered volume of aerosol or the like. It also can be in less discrete forms such as a bulk liquid or suspension, although this is usually less preferred in situations where the delivery of the amount of drug is to be controlled.

In most cases the medication event is detected inferentially such as by noting the removal of a dose of drug from a container, by noting an opening and/or closing of an openable/closable drug container or by noting some other handling of a drug container consistent with the taking of a dose of its drug from it, for example inverting the container. These events can be detected electronically by the use of a motion sensitive switch or a drug-container closure-actuated switch providing a detectable electrical signal. Any other means for sensing a medication event and generating a detectable electrical signal as the result can be used as well.

The devices of the invention provide two pieces of compliance information to the patient. One piece of information is the time that has elapsed since the patient's last medication event (dose taking). This information can be

generated by a resettable running clock within the device with its output reset and controlled by medication event signals. It can also be derived from a continuous running clock signal with a suitable subtraction of the time of the detected medication events.

The other piece of information is the number of medication events which have occurred on a daily basis, i.e. the number of medication events that the device has detected during the given day.

These pieces of information are provided to the patient in any patient-recognizable form. This can include visual information displayed on LED or LCD arrays, audible signals indicative of the time and count values or information from a speech synthesizer provided through an annunciator, or the like. The two pieces of information usually are presented sequentially, if presented audibly. If presented visually, they can be presented simultaneously on a pair of displays or sequentially on a single display.

The daily dose count information which the device provides to the patient can be generated in any of several ways. In one embodiment a readable count memory stores the number of medication events detected. This value is displayed and this memory is reset to zero before or at the beginning of each day. In another embodiment the memory is not reset to zero at the beginning of the day but instead the total number of doses is accumulated and this total is noted at the end of each day and a value for the difference between the running total and the preceding night's total is displayed to provide the daily dose information. Other methods may be used as well.

A presently preferred embodiment of the invention is illustrated in FIGs. 1 and 2 in which it is shown incorporated in the closure 3 of a medication container, here shown as a pill bottle. In FIG. 1 closure 3 and container 2 are connected by an interlocking mechanism of any of the various known types for use with the type of drug or medicament being delivered. The device includes a display readable by the user at any time. As detailed in FIG. 2. in the device of FIG. 1 display 4 is located in the top area of

closure 3. Display 4 consists of a first display 5 for indicating the number of dosages taken since last reset, and a second display 6 showing the elapsed time since the last drug dosage taken. Both displays 5 and 6 can be multi-digit displays. Display 6 may include digits to show days, hours, minutes, and/or seconds.

To recognize that a drug dose was taken, the interlocking mechanism of closure 3 and container 2 include a switch (not shown in FIG. 1 or FIG. 2) which is activated each time the closure 3 is removed from the container 2 or replaced on the container. This switch serves as a sensor (detector) and provides a signal to the electronic section of the medication reminder device. This signal may be subjected to any of many filters or validation techniques to assure that it is in fact an accurate indication of actual medication events. Such techniques are taught in the art and do not, in and of themselves constitute an aspect of this invention.

The signal resulting from the detected medication event is electronically noted in the device and used to start the generation of an elapsed time signal within the device. The device of the invention includes an elapsed time clock determining the time elapsed since the last medication event. This elapsed time signal is reset to zero whenever a medication event is detected. This can be done by zeroing the clock, by subtracting the most recent medication event time from a running real time value generated by the clock, or the like. This elapsed time signal is used to provide the "time since last dose" information provided to the patient through the display.

The device also includes a counter for recording the number of medication events detected. Each time the sensor detects that a medication event has occurred, this counter is advanced. The clock provides a "day" signal which serves as a basis for determining the beginning of successive "day" or twenty four hour time periods. When this day signal is generated, once every 24 hours, the number provided by this counter is reset. The reset time defines the medication day, a 24-hour time period. This reset time does not have to

coincide with midnight or any other significant time instant during a 24 hour day. Resetting of the 24 hour medication event counter preferably occurs while the user is normally sleeping, e.g. at 3 a.m. The resetting can take the form of zeroing the counter or by recording a start value which will be subtracted from the counter value throughout the upcoming day. This value from the counter is used to provide the "number of doses taken today" information provided to the patient through the display.

The time signal may merely provide the information needed for the 24 hour day determination and the time since last dose determination. It may, if desired, also provide information on the time of day and the date such that when the time signal and detector signal are correlated or otherwise associated with one another it results in a notation of the date and time of day when the medication event occurred. This information can be used in those embodiments of this invention in which the device further includes a readable memory for storing the dates and times when medication events occurred.

FIG. 3 is a schematic illustration of a generalized electronic section of the present invention. The electronic section includes a clock 40 providing timing signals. Memory 24 is used to store control information for processor 42, detected medication event information and other information to operate the device.

The display section consists of a display controller 43 and two displays 5 and 6. An input/output interface 44 allows the health care professional to load data into the apparatus and to read data from the apparatus via port 46 in those embodiments which call for this function. Sensor 20 signals to processor 42 when a medication event is detected. A battery 45 supplies electrical power to the electronic section.

FIG. 3 is a more detailed schematic illustration of the electronic section of the apparatus of the present invention. Upon installation of the battery and initial setting of real-time clock 22 clock generator 40 provides clock pulses to operate real-time clock 22, 24 hour clock 25, and elapsed

time counter 51. Electronic sensor 20 issues a signal whenever a medication event is sensed. The signal from electronic sensor 20 resets and restarts elapsed time counter 51 and causes storage of real time data provided by real time clock 22 in memory 23 (as indicated by AND gate symbol). Elapsed time counter 21 may be a separate counter or may be implemented as read, increment and store operation using an internal register of processor 42 or a store location of memory 24.

Once a day medication event counter 26 is reset to zero. This incident is controlled by 24 hr clock 25. This reset/restart event is taken as a start of medication day time and does not have to coincide with midnight, but may be set at about 3 a.m. when most users are at rest.

Display controller 43 interfaces with processor 42, which includes the function of elapsed time counter 51 and drug use counter 26. Display controller 30 processes information from elapsed time counter 51 and drug use counter 26 for display on first display 5 and second display 6.

Additional data, such as date and time of day, may be displayed in multiplex mode or selectively on the same displays or constantly on additional displays.

In some versions of the present invention the electronic section includes an electronic interface 44 for communication with external devices. Such an external device may provide certain data of a drug regimen for storage in memory 24 or may read compliance information from memory 24 for use in equipment external to the device of the present invention.

In other versions of the present device the functions of elapsed time counter 26, real-time clock 22, 24 hr clock 25, drug event counter 26, and display controller 43, as well as other data handling functions represented by block 49 in FIG. 3 may be implemented in software and performed by a microprocessor.

As already described in the Statement of the Invention, a number of additional or alternative functions can be provided to adapt the device to particular applications. One of these additional or alternative functions is generating an indication if the rate of medication events deviates from a

predetermined regimen. To achieve this function, the device must be provided with a value for the desired rate of dosing such as through interface 44. This can be implemented by inserting such a rate value into a suitable memory, by inserting an ideal or maximum medication event count for a given time period, such as a day, into memory or into a suitable wired circuit or the like. This input rate is then compared in real time with the actual rate of dosing determined by the number of medication events detected and the length of time over which they were detected.

For this type of operation regimen data are loaded from an external source via IP/OP interface 44 into memory 24. Processor 42 can generate variance data and issue an indicator for display on displays 5 and 6. In a similar fashion processor 42 can cause the issue of an indicator for display on displays 5 and 6. In a similar fashion processor 42 can cause the issue of an indicator in audible format by controlling an acoustic device or via a speech synthesizer generate the appropriate message. The devices for generating indicator information in audible format are known in the art and are shown in block diagram form in FIG. 3 an audible embodiment of display 43.

If the detected rate falls within the desired parameters one sort of indication can be provided to the patient. If the detected rate falls outside the desired parameters another indication can be provided. These differing indications can be provided by a separate visual or audible message. A visual indication may be identified by an alternating display of a character, like an "X", and the variance information or actual dose information. The indication may also be given in audible format.

In the case where a visual display is involved it is generally preferred, for cost and simplicity advantages, to display information about rate compliance together with one or both of the two main displays of "time since last dose" and "number of doses taken today." This can be accomplished in any appropriate manner. We prefer to provide no special signal if the dosing rate is appropriate and to partially or completely override one or both of the two main displays with

an alerting signal if the dosing rate deviates inappropriately. This override can take the form of replacing the main display signal with a warning signal, interspersing the warning signal among regular display signals, varying the color or contrast of a main display signal or the like. Depending upon the nature of the rate deviation and its seriousness, this warning signal may continue until reset by the patient's health care professional, may reset automatically when the rate returns to an acceptable level, may reset automatically after an appropriate period of time, such as the beginning of the next successive "day", or may be cancelled or acknowledged by the user using an acknowledge button.

In a simple and preferred embodiment the rate information is provided in the form of a daily maximum dose count and a rate deviation is detected if the daily dose count exceeds this maximum.

The above disclosure relates to doses of drug taken in a 24 hour period and the time elapsed since the last dose was taken. The device is incorporated in the cover of the drug container such as a pill or liquid medication bottle. It recognizes when and how often the container is opened or accessed. The device can be used in combination with other types of containers of medications and medicinal devices to provide compliance information by detecting when the contents of the container is accessed. This device provides information for display to the user about the number of medication events and the time elapsed since the last medication event. The function can be expanded to show variances detected between the actual medication events and the prescribed medication regimen, to show excess doses, and to provide indicators if predetermined variance situations are detected.

The device may issue dose time reminders which are initiated by processor 42 using regimen data stored in memory 24 via the IP/OP interface 44 by a health care professional. The dose time reminder could be a visual display of a symbol or character, or as an audible alarm signal. Visual display of the reminder and the audible alarm can be adapted to

particular conditions related to the type of container and medication.

WHAT IS CLAIMED IS:

1. A dosing information device for patient and health care professional use comprising in combination:

a detector for detecting medication events,

an elapsed time counter providing time information on time elapsed since the most recent detecting of a medication event,

a number counter for providing a number count of medication events detected on a daily basis,

means for indicating to the patient the number count of medication events provided by the number counter and the time information provided by the elapsed time counter,

a readable memory for storing a record of the medication events detected by the detector, and

means for providing to the health care professional upon demand the record of medication events stored in the memory.

2. The dosing information device of claim 1 in combination with a medication container, wherein said medication events the detector detects involve the medication container.

3. The dosing information device of claim 2 wherein the container is an openable/closable container and wherein the detector detects events involving opening/closing of the container.

4. The dosing information device of claim 1 wherein said means for indicating to the patient the number count of medication events and the elapsed time is a visual display.

5. The dosing information device of claim 1 wherein said means for indicating to the patient the number count of medication events and the elapsed time is an audible annunciator.

6. The dosing information device of claim 1 additionally comprising

an event time counter providing event time information on a time of each detecting of a medication event, and wherein this event time information is included in the record of medication events.

7. The dosing information device of claim 1 additionally comprising means for storing a prescribed regimen for medication and means for issuing a dose reminder for indicating the times for medicating in accord with the prescribed regimen.

8. A dosing information device for patient use comprising in combination:

a detector for detecting medication events,

an elapsed time counter providing time information on time elapsed since the most recent detecting of a medication event,

a number counter for providing a number count of medication events detected on a daily basis,

means for indicating to the patient the number count of medication events provided by the number counter and time information provided by the elapsed time counter,

means for determining an actual rate of medication events from said time information and said number count,

means for storing an acceptable rate for medication events,

means for comparing the acceptable rate with the actual rate and determining when the actual rate deviates from the acceptable rate and

means for indicating to the patient when the actual rate deviates from the acceptable rate.

9. The dosing information device of claim 8 in combination with a medication container, wherein said medication events the detector detects involve the medication container.

10. The dosing information device of claim 9 wherein the container is an openable/closable container and wherein the detector detects events involving opening/closing of the container.

11. The dosing information device of claim 8 wherein said means for indicating the number count of medication events and the elapsed time to the patient is a visual display.

12. The dosing information device of claim 8 wherein said means for indicating to the patient the number count of medication events and the elapsed time is an audible annunciator.

13. The dosing information device of claim 8 wherein the means for indicating when the actual rate deviates from the acceptable rate is an override of at least one of the means for indicating to the patient the number count of medication events provided by the number counter and the means for indicating to the patient time information provided by the elapsed time counter.

14. The dosing information device of claim 13 wherein said means for indicating to the patient the number count of medication events provided by the number counter and the means for indicating to patient the time information provided by the elapsed time counter are visual displays.

15. The dosing information device of claim 8 additionally comprising means for storing a prescribed regimen for medication and means for issuing a dose reminder for indicating times for medicating in accord with the prescribed regimen.

16. A dosing information device of claim 8 wherein the acceptable rate is a maximum rate and wherein deviation from the acceptable rate is an exceeding of the maximum rate.

17. The dosing information device of claim 16 in combination with a medication container, wherein said medication events the detector detects involve the medication container.

18. The dosing information device of claim 17 wherein the container is an openable/closable container and wherein the detector detects events involving opening/closing of the container.

19. The dosing information device of claim 16 wherein said means for indicating to the patient the number count of medication events and the elapsed time is a visual display.

20. The dosing information device of claim 16 wherein said means for indicating to the patient the number count of medication events and the elapsed time is an audible annunciator.

21. The dosing information device of claim 16 wherein the means for indicating when the actual rate deviates from the acceptable rate is an override of at least one of the means for indicating to the patient the number count of medication events provided by the number counter and the means for indicating to the patient the time information provided by the elapsed time counter.

22. The dosing information device of claim 21 wherein said means for indicating to the patient the number count of medication events provided by the number counter and the means for indicating to the patient time information provided by the elapsed time counter are visual displays.

23. The dosing information device of claim 16 additionally comprising means for storing a prescribed regimen for medication and means for issuing a dose reminder for indicating times for medicating in accord with the prescribed regimen.

24. A method for monitoring and enhancing a patient's compliance with a drug dosing regimen comprising

determining a 24-hour time period,

electronically detecting each member of a series of medication events,

resetting to zero an elapsed time clock whenever a medication event is detected and determining time elapsed after resetting,

indicating to the patient said time elapsed,

determining the 24-hour total number of medication events detected during said 24-hour time period

indicating to the patient said 24-hour total number, and storing in a readable memory a record of the detected medication events.

25. The method of claim 24 said method further comprising

associating each member of the medication events with time information related to its occurrence, and

storing said time information in the memory.

26. The method of claim 24 said method further comprising

storing in memory a prescribed regimen for the medication events and

issuing a dose reminder to the patient to indicate the times for medicating in accord with the prescribed regimen.

27. A method for monitoring and enhancing a patient's compliance with a drug dosing regimen comprising

storing in a memory an acceptable rate for medication events,

determining a 24-hour time period,

electronically detecting each member of a series of medication events,

resetting to zero an elapsed time clock whenever a medication event is detected and determining time elapsed after resetting,

indicating to the patient said time elapsed,

determining a 24-hour total number of medication events detected during said 24-hour time period,

indicating to the patient said the 24-hour total number,

determining an actual rate at which medication events are being detected based upon said time elapsed,

comparing the actual rate with the acceptable rate and indicating to the patient when the determined rate deviates from the acceptable rate.

28. The method of claim 27 said method further comprising storing in memory a prescribed regimen for the medication and

issuing a dose reminder to the patient to indicate the times for medicating in accord with the prescribed regimen.

29. A method for monitoring and enhancing a patient's compliance with a drug dosing regimen comprising

storing in a memory a maximum rate for medication events,

determining a 24-hour time period, electronically detecting each member of a series of medication events,

resetting to zero an elapsed time clock whenever a medication event is detected,

indicating to the patient elapsed time shown by the elapsed time clock,

determining a 24-hour total number of medication events detected during the 24-hour time period,

indicating to the patient the 24-hour total number,

determining an actual rate at which medication events are being detected,

comparing the actual rate with the maximum rate and

indicating to the patient when the actual rate exceeds the maximum rate.

30. The method of claim 29 said method further comprising

storing in memory a prescribed regimen for the medication and

issuing a dose reminder to the patient to indicate times for medicating in accord with the prescribed regimen.

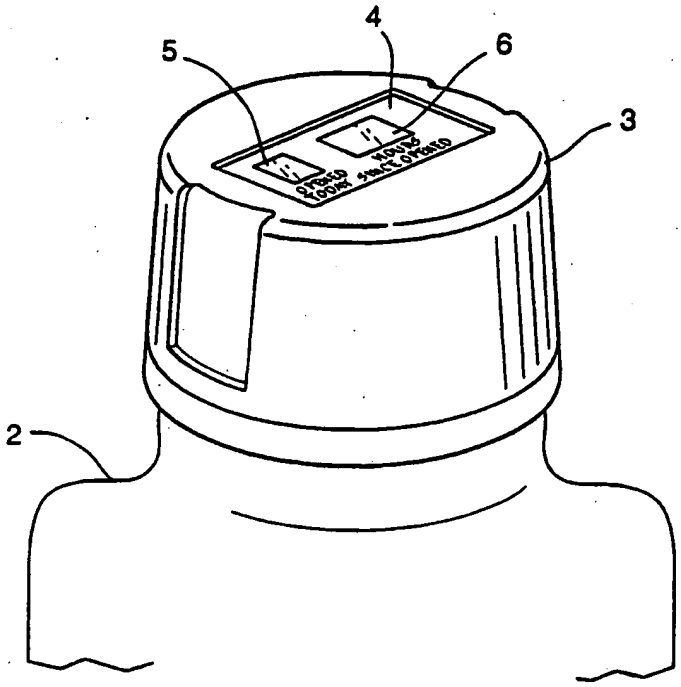


FIG. 1

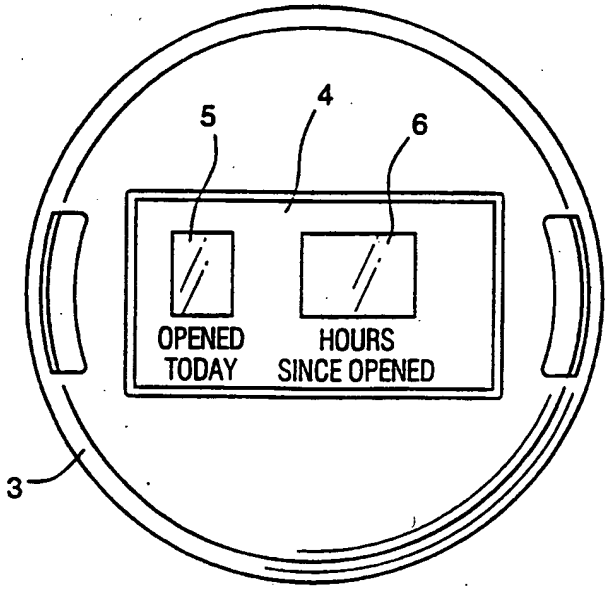
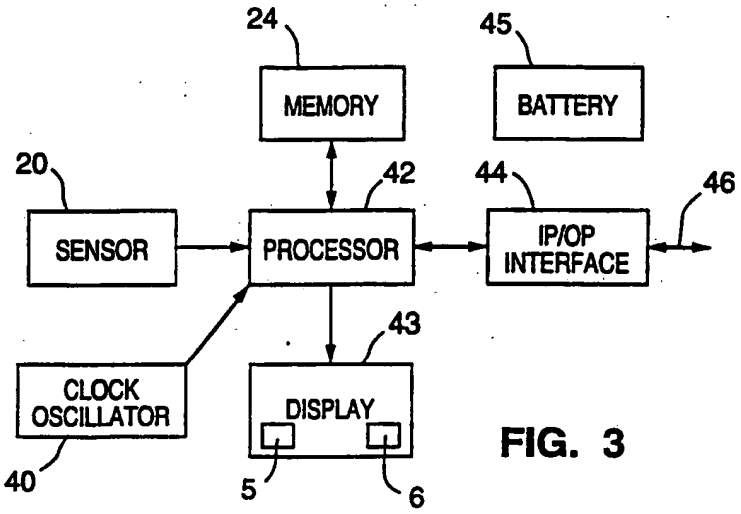


FIG. 2


24
MEMORY
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BATTERY
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SENSOR
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PROCESSOR
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IP/OP INTERFACE
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CLOCK OSCILLATOR
DISPLAY
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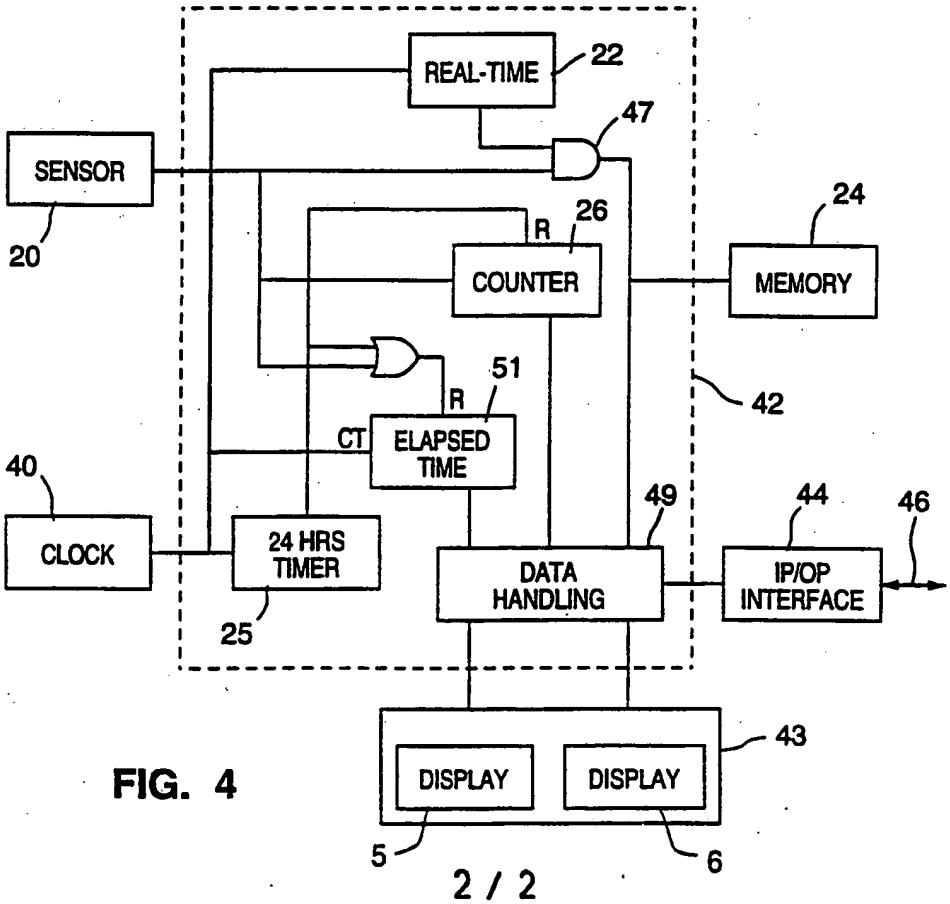
FIG. 3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25
49
44
46
DATA HANDLING
IP/OP INTERFACE
43
DISPLAY
DISPLAY
5
6

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/11035

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :G04B 47/00
US CL :128/630; 221/2
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/630; 221/2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

116/308; 128/897, 898; 141/22; 221/2; 604/19, 27, 28, 246

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,970,669, (McINTOSH ET AL.), 13 November 1990. See entire document.	1-30
X	US, A, 4,695,954, (ROSE ET AL.), 22 September 1987. See entire document.	1-30
Y	US, A, 4,674,652, (ATEN ET AL.), 23 June 1987. See entire document.	1-30
Y	US, A, 4,617,557, (GORDON), 14 October 1986. See entire document.	1-30
Y	US, A, 4,588,303, (WIRTSCHAFTER ET AL.), 13 May 1986. See entire document.	1-30
Y	US, A, 4,419,016, (ZOLTAN), 06 December 1983. See entire document.	1-30

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
02 DECEMBER 1994

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13 FEB 1995

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PCT/US94/11035

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,360,125, (MARTINDALE ET AL.). 23 November 1982. See entire document.	1-30